FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Arthritis Advisory Committee (AAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
May 8, 2012

DRAFT AGENDA

The committee will discuss supplemental biologics license application 125249, ARCALYST (rilonacept) injection, Regeneron Pharmaceuticals, Inc., for the following proposed indication: "ARCALYST (rilonacept) is an interleukin-1 blocker indicated for the prevention of gout flares during initiation of uric-acid lowering therapy in adult patients with gout. ARCALYST has not been studied for longer than 16 weeks in this clinical setting."

8:30 a.m.	Call to Order and Introduction of Committee	**Lenore Buckley, M.D.** Chairperson, AAC
8:35 a.m.	Conflict of Interest Statement	**Philip Bautista, Pharm.D.** Designated Federal Officer, AAC
8:40 a.m.	FDA Introductory Remarks	**Sarah Yim, M.D.** Associate Director Division of Pulmonary, Allergy & Rheumatology Products (DPARP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:50 a.m.	**SPONSOR PRESENTATIONS**	**Regeneron Pharmaceuticals, Inc.**
	Introduction	
	Gout: Disease Awareness and Unmet Medical Need	
	Clinical Development and Efficacy	
	Safety	
	Clinical Perspective	
10:20 a.m.	Clarifying Questions to Sponsor	
10:35 a.m.	**BREAK**	

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DRAFT AGENDA (cont.)

10:50 a.m.	**FDA PRESENTATIONS**	
	Overview of Clinical Program	
	Efficacy Considerations	
	Safety and Risk/Benefit Considerations	
12:00 p.m.	Clarifying Questions to the FDA	
12:15 p.m.	**LUNCH**	
1:15 p.m.	Open Public Hearing	
2:15 p.m.	Charge to the Committee	**Sarah Yim, M.D.**
2:25 p.m.	Questions to the Committee and Committee Discussion	
3:30 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committee and Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	